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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,452

11/24/2003

Scott Gubler

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34013 7590 07/07/2009  
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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/720,452	GUBLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-21,23-31 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-21, 23-31, 42-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/2009 has been entered.

Currently, claims 1, 3-21, 23-31, 42-44 are pending and are under examination herein.

### ***Response to Arguments***

Applicants argue over the 35 USC 102(b) rejection over Hunsicker. In particular, Applicants argue that Hunsicker does not disclose the step of dry mixing a binder with tocopheryl succinate. Applicants also argue that Hunsicker does not use a high shear granulator. Applicants point to the newly amended claims that the binder is dry mixed with the tocopheryl succinate which ultimately results in a greater concentration of tocopheryl succinate. Applicants assert that Hunsicker does not address this issue. Applicants further argue that Hunsicker does not teach establishing a bowl temperature in the granulator between about 30-32 degrees C.

It is noted that Hunsicker does not specify dry mixing a binder with the tocopheryl succinate; however, Hunsicker teaches the same methods of mixing a binder with

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tocopheryl succinate and the subsequent steps as claimed. Applicants assert that the steps as presently claimed ultimately result in a greater concentration of tocopheryl succinate and point to the specification at paragraphs 0016-0018 to strengthen the argument. This argument has been considered and is not found persuasive because there is nothing in the claims or in the specification to lead one to believe that there is a greater concentration of tocopheryl succinate in the present composition compared to the prior art. Hunsicker teaches that the tocopheryl granules consist of about 85 to about 99.5% of tocopheryl succinate on a dried basis (Col. 5, lines 64-67 – Col. 6, line 1) which are then used for the manufacture of tocopheryl succinate-containing tablets and capsules. Absent a showing of unexpected results, there is no indication in the present claims or specification that the method used by Applicants results in better properties, e.g. a higher concentration of tocopheryl succinate granules, compared to the prior art of Hunsicker. Therefore, the reference is being used in a new grounds of rejection given below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-21, 23-31 and 42-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Hunsicker (US Patent 6,130,343) in view of Anderson et al. (US Patent 2,791,584).

Hunsicker et al. teaches a method for making a tocopheryl product which comprises providing an amount of tocopheryl succinate and binder (Col. 3, lines 1-5). The process involves spray-coating the tocopheryl succinate with a solution containing a binder in a fluidized-bed granulation apparatus (Col. 3, lines 11-20). Water is typically employed as the solvent, though it is taught that organic solvents can also be used in the solution for spray coating (Col. 4, lines 12-16 and 55-58). Example 1 teaches mixing tocopheryl succinate and a binder and spraying a liquid mixture of the binder and water into the mix all within a fluidized-bed granulation apparatus (Col. 7, lines 17-38). The mixture of the water and the binder is about 10% by weight, which falls within the ranges taught in claims 13-14 (Example 1). The temperature in the granulator has a maximum setting of 30°C, which falls within the ranges taught in claims 15-16 (meeting the limitation of the term “about”; Example 1). Hunsicker et al. teaches that the product should be maintained in a fluidized state until the desired degree of evaporation has been obtained (meeting the limitation of claims 17 and 29; Col. 5, lines 50-55). It is also taught that the moisture of the product in the bed is tested periodically (meeting the limitation of claims 18 and 30; Example 1). The tocopheryl succinate granules can be used in the manufacture of tablets (meeting the limitation of claim 19; Col. 6, lines 25-46). Examples of water-soluble binders include celluloses (meeting the limitation of claim 44; Col. 4, lines 17-19).

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Hunsicker et al. do not specifically teach heating the water to a temperature above 80 degrees C before spraying the liquid onto the mixture nor the use of a high shear granulator.

Anderson et al. teach a method of heating a binder, in particular a methyl cellulose, in an effort to dissolve the methyl cellulose and have a more uniform distribution of water throughout the mass of methyl cellulose (Col. 2, lines 19-40). It is taught that the treatment is most preferably carried out at a temperature above 70°C. See in particular Example 1 in which methyl cellulose was mixed with water at 80°C.

Accordingly, it would be obvious to a person having ordinary skill in the art at the time of the invention to heat the water of the Hunsicker et al. invention to a temperature above 80 degrees C as taught by Anderson et al. One would be motivated to do this in an effort to completely dissolve the binder in the water in an effort to spray over the tocopheryl succinate.

It is noted that the limitation that the mixing of the binder solution with a tocopheryl succinate substance in a high shear granulator is obvious in light of the above rejections. It is noted that both the present invention and the prior art teach granulation and the result is a tocopheryl product. Absent a showing of unexpected results that the tocopheryl product is somehow different with a high shear granulator compared to a fluidized-bed granulator, the present invention is deemed obvious over the prior art.

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Furthermore, it has been held that merely changing the order of steps in a multi-step process is not a patentable modification absent a showing of unexpected results.

*Ex parte Rubin* 128 USPQ 440 (POBA 1959.)

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617